

**REMARKS**

In an Office Action dated October 8, 2004, claims 1-20 and 22-24, all of the claims then under consideration in the above-identified application, were rejected. In addition, claims 23 and 24 were objected to. In response to the Office Action, Applicants are amending independent claim 1 and canceling dependent claims 12, 23 and 24.

The amendments should entered at this time, since they are being made merely to address issues first raised in the last Office Action, are completely in line with Applicants' prior arguments, and incorporate the elements of claim 12 into claim 1. The above amendments do not raise new issues that would require further consideration and/or search. The amendments raise no issue of new matter. By addressing the issues raised in the final Office Action, the amendments place the application in condition for allowance, or in better form for appeal by materially reducing and simplifying the issues for appeal. In view of the above, the amendments should entered.

In view of the amendments and the following remarks, Applicants respectfully request reconsideration of this application, and allowance of all of the presently pending claims, as amended.

Claims 23 and 24 were objected to as a substantial duplicate of claims 2 and 3. Claims 23 and 24 have been cancelled, obviating this objection.

Claims 1-6, 10, 15, 16, 18-20, 23, 24 were rejected under 35 USC §103(a) as being unpatentable over Abdul-Malak U.S. Patent No. 5,567,807 in view of Stone et al. U.S. Patent No. 5,624,463 (Stone). Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

Abdul-Malak discloses a Type I or III collagen membrane.

Abdul-Malak fails to disclose or suggest a barrier layer that has at least one smooth face so as to inhibit cell adhesion thereon, said barrier layer further having a fibrous face opposite said smooth face, wherein said matrix layer is adhered to said fibrous face. Abdul-Malak fails to disclose a separate matrix of collagen II adhered to the barrier layer. Abdul-Malak fails to disclose a matrix layer having a thickness of about 0.2-12mm and which has a matrix structure which consists essentially of collagen II having an open sponge like texture.

Stone discloses a two piece device having a matrix layer 12 and a rigid base component 20. Stone's matrix layer 12 may include collagen II, and is oriented away from the damaged area.

The rigid base component may contain hydroxyapatite and collagen, or TCP and collagen, but does not consist essentially of collagen II. Stone's configuration, to the extent that it is relevant, if at all, is directly opposite of that presently claimed. Contrary to Stone, the matrix layer of the present invention is oriented toward the damaged area, instead of away from it.

Stone's device is a prosthetic threaded scaffold which is screwed into a joint injury. The threaded scaffold of Stone clearly is not a "sheet" as required by the present claims. Moreover, Stone fails to provide any hint or suggestion of utilizing a multi-layer "sheet" of collagen membrane material as specified in the present claims. The claims recite that the barrier layer has a thickness of about 0.2-2mm and the matrix layer of the multi-layer sheet has a thickness of about 0.2-12mm.

The combination of Abdul-Malak and Stone fails to suggest that the barrier layer has at least one smooth face so as to inhibit cell adhesion thereon, said barrier layer further having a fibrous face opposite said smooth face, wherein said matrix layer is adhered to said fibrous face.

Abdul-Malak and Stone cannot be combined to suggest the present claims. Persons of ordinary skill in the art, taking in consideration the teachings of the art, would combine Abdul-Malak and Stone, if at all, by orienting the matrix layer of Stone away from the damaged area, and not toward the damaged area as required by the present claims.

In view of the above remarks, withdrawal of the rejection based on Abdul-Malak in combination with Stone is respectfully requested.


Claims 7, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Malak in view of Stone et al. and further in view of Geistlich et al. WO 95/18638. Claims 8 and 9 were rejected under 35 USC §103(a) as being unpatentable over Abdul-Malak in view of Stone et al. and further in view of Sonis WO 90/13302. Claim 11 was rejected under 35 USC §103(a) as being unpatentable over Abdul-Malak in view of Stone et al. and further in view of Caplan et al. U.S. Patent No. 5,197,985. Claims 13 and 14 were rejected under 35 USC §103(a) as being unpatentable over Abdul-Malak in view of Stone et al. and further in view of Geistlich et al. U.S. Patent No. 5,573,771. Claim 17 was rejected under 35 USC §103(a) as being unpatentable over Abdul-Malak in view of Stone et al. and further in view of Seid US Patent No. 5,254,133. Insofar as these rejections could apply to the claims, as amended, they are respectfully traversed.

The above discussion concerning the deficiencies of the Abdul-Malak/Stone combination is equally applicable here and incorporated herein by reference. None of the Geistlich et al. '638, Sonis, Caplan et al., Geistlich et al. '771, or Seid references supply the above-noted deficiencies of the Abdul-Malak/ Stone combination. In view thereof, withdrawal of the rejections based on Abdul-Malak in view of Stone, and Geistlich et al. '638, Sonis, Caplan et al., Geistlich et al. '771, or Seid is respectfully requested.

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Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,

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